

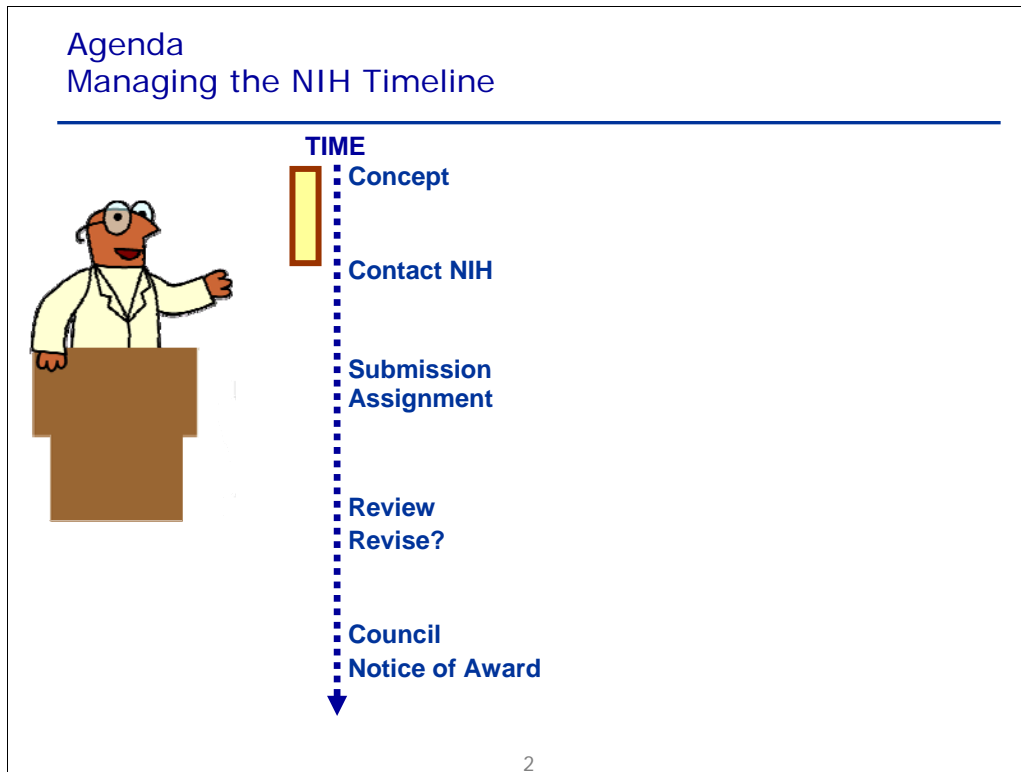
Advice on NIH SBIR & STTR Grant Applications
Managing the NIH Timeline



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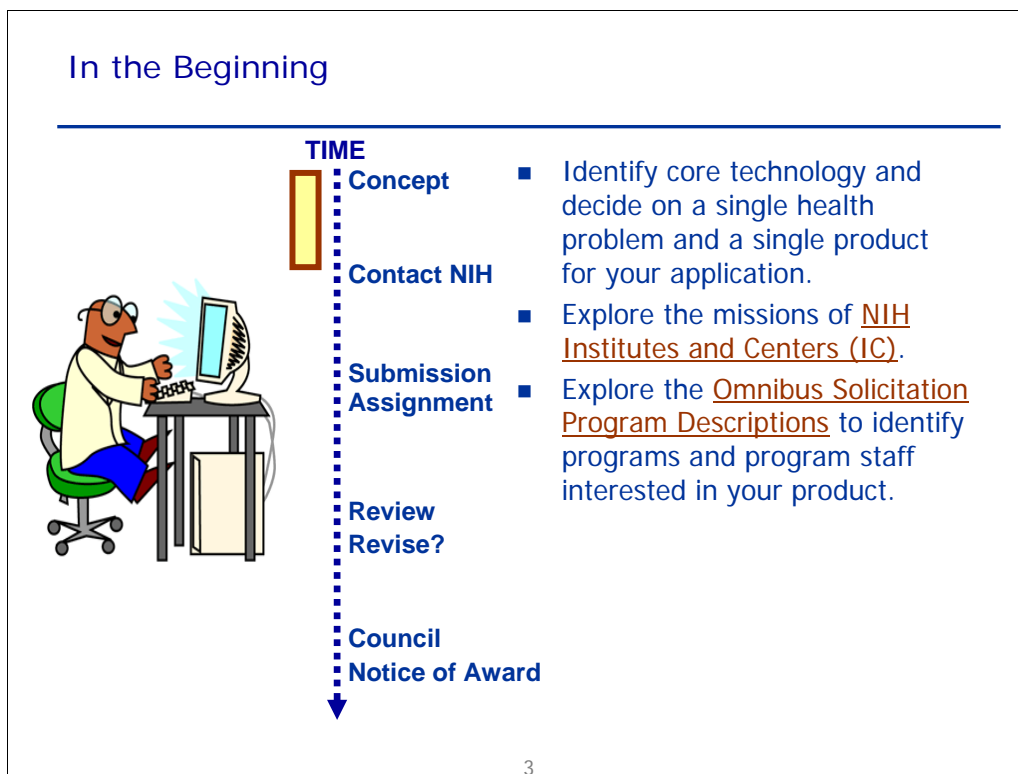
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Hello, I am Gregory Milman. In these presentations I provide advice on the NIH SBIR and STTR programs. This module is titled Managing the NIH Timeline. It was updated in July 2009. Send your comments, suggestions, and criticisms to gmilman@niaid.nih.gov.



Agenda - Managing the NIH Timeline

The slides in this presentation display a timeline illustrated by an arrow that runs from your concept for a product to NIH's issuing a Notice of Award. A rectangle shows the place along the timeline where events occur.



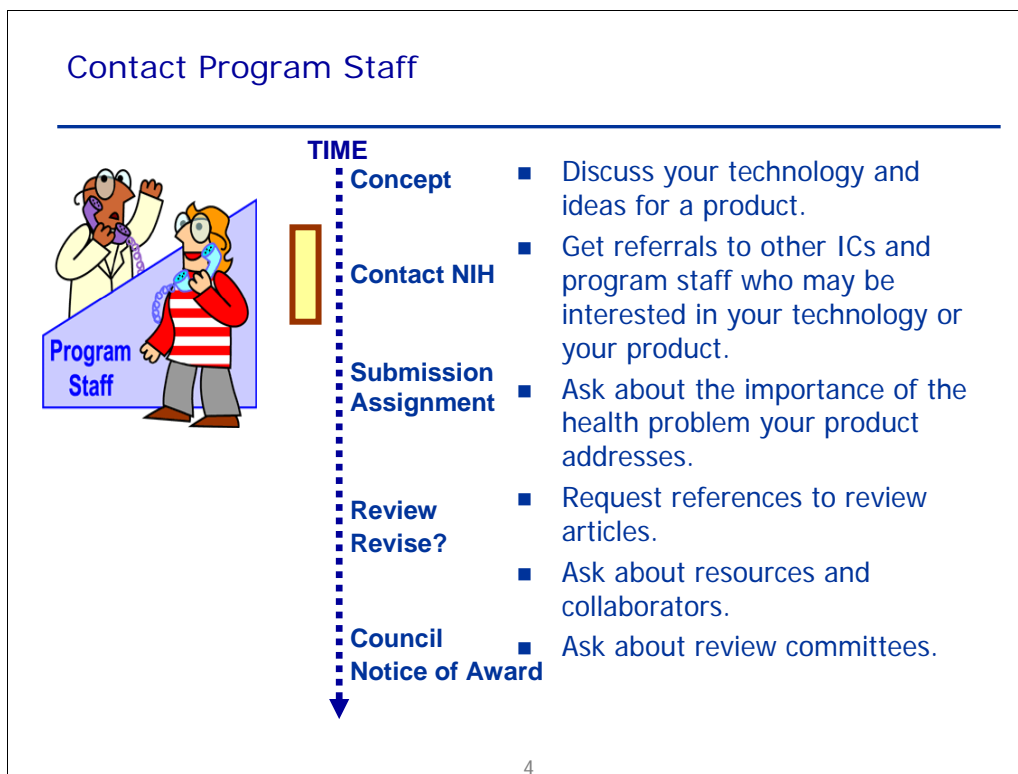
In the beginning

Identify your core technology and decide on a single product for a single health problem that will be the focus of your application. I advise one and only one problem, and one and only one product in each application.

Click on the NIH Institutes and Centers (ICs) link to explore IC missions and identify those likely to fund your application.

Explore the Omnibus Solicitation Program Descriptions to identify those programs and program staff who may be interested in your product.

Now you are ready to contact NIH staff.



Contact Program Staff

Discuss your technology and product ideas with program staff you identify. You may learn that your technology, your product, or both are more appropriate to a different program.

Ask for referrals to other ICs and program staff who may be interested in your technology or your product ideas.

Ask program staff about the importance of the health problem your product addresses. Talk about research trends, unmet needs, and your product's competition. Ask for references to review articles that may help you prepare your Background and Significance section.

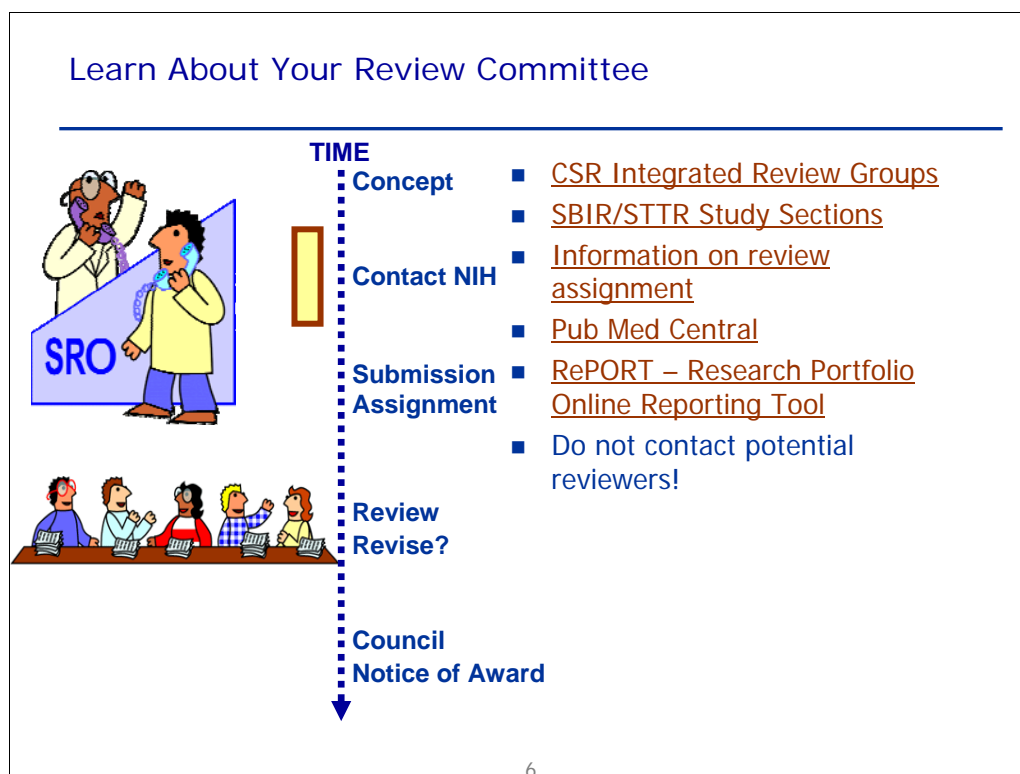
Ask program staff to identify resources and potential collaborators at NIH or elsewhere.

Also ask them which scientific review officer (SRO) and review committee are likely to be assigned your application.



Contact Grants Management Staff

You will mainly interact with grants management staff while you negotiate your award and later when you manage your grant. However, you may want to talk with them before submitting an application if you have questions on administrative matters. These include budgets, rules and regulations, and policy issues on human subjects and vertebrate animals.



Learn About Your Review Committee

Your review committee is the primary customer for your application. You should learn as much as possible about potential reviewers, though you may find it difficult to identify the Special Emphasis Panel (SEP) for your submission. To find an SEP, scroll down the Center for Scientific Review (CSR) descriptions of Integrated Review Groups (IRGs) and select a link to the topic that encompasses your product's health problem. You will see a list of study sections within the IRG. Select the link to each of the small business panels and read the panel description for its relevance to your product. Each panel has links to the scientific review officer (SRO) and rosters and for recent meetings. You may be able to contact the SRO to learn if your proposal would fit within his or her SEP.

The rosters enable you to identify reviewers. Some of these reviewers, particularly those who have participated in more than one meeting, may be on the review panel for your application. I encourage you to learn about these potential reviewers. You can use the National Library of Medicine's Pub Med Central site to search for publications by author. Pay particular attention to the publications of those reviewers likely to receive primary assignment of your application. You can also use the NIH RePORT – Research Portfolio Online Reporting Tool database to learn if potential reviewers have NIH-funded projects and read abstracts of their proposals.

Please avoid any temptation to contact potential reviewers! They do not want to hear from you.



Before Writing Your Application

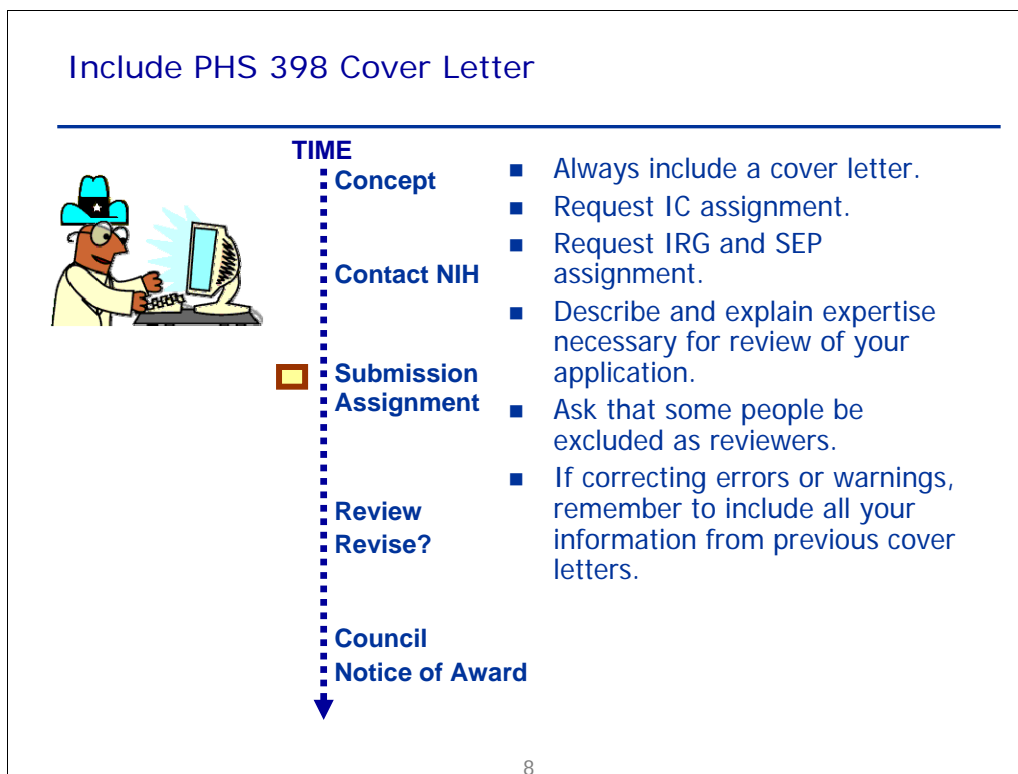
Many applicants delay forming and registering their companies until just before submitting their applications, and as a result, fail to meet an application receipt date. I suggest you complete the following before writing your application.

Select a principal investigator, explore strategic partnerships, and arrange for space and resources if your application gets funded.

Decide on your company name, obtain an Employer ID Number (EIN) and open a company bank account.

Obtain Data Universal Number System (DUNS) and register with Central Contractor Registration (CCR) for Federal Government, Grants.gov and the eRA Commons.

Review and follow the NIH Electronic Submission of Grant Applications pathway.



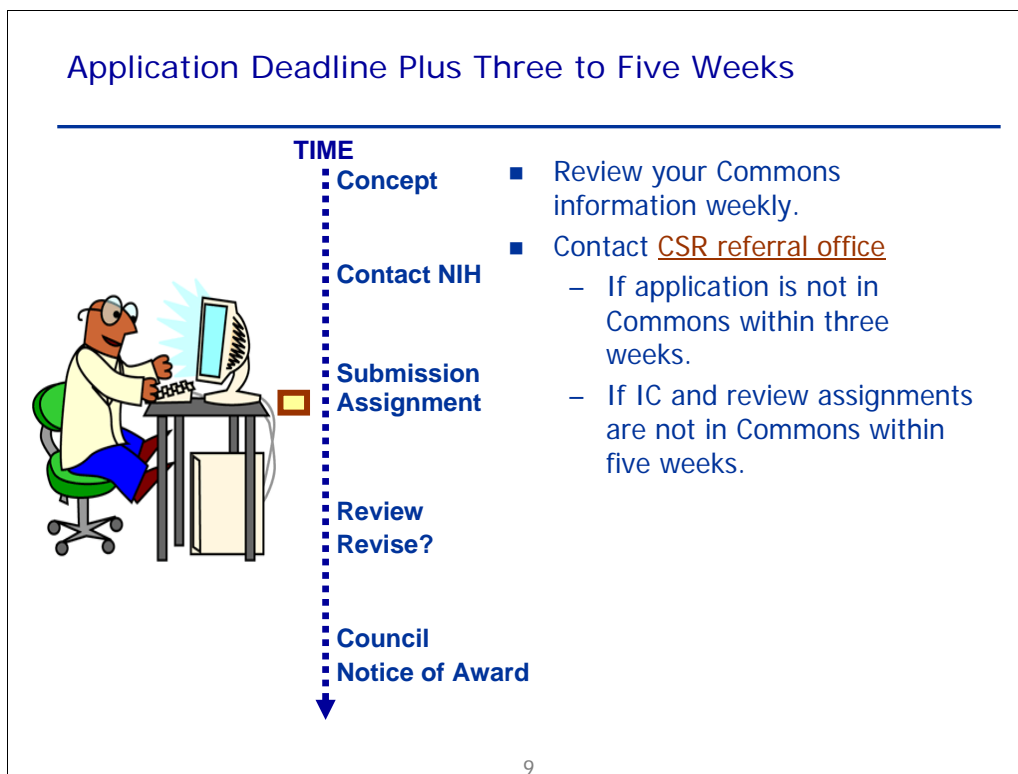
Include PHS 398 Cover Letter

Even though it appears optional, you should definitely include a PHS 398 Cover Letter. Your Cover Letter provides information to CSR and is not read by reviewers. Follow the suggested Cover Letter format in the SF424 SBIR/STTR Application Guide.

Failure by CSR to honor your Cover Letter requests is your only significant justification for asking an IC's Council to send your application to another SEP for re-review without having to revise and resubmit your application. After careful consideration include the following:

- Request your application's assignment to an IC, and to a IRG and SEP and give your reasons.
- Describe disciplines and expertise required to review your proposal. This is very important.
- List people (e.g., competitors) who should not review your application and why. Be careful though! If you exclude too many reviewers, your application may be placed in a panel with little expertise in your scientific area. Never suggest reviewers for your application.

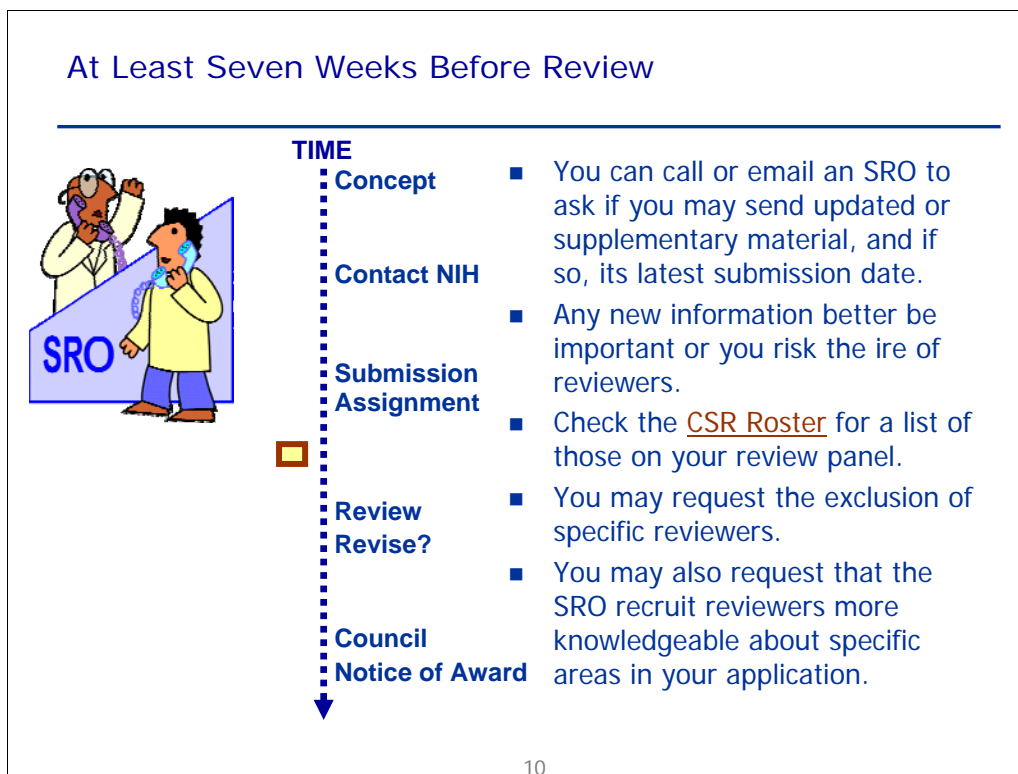
Remember to include all your information again if you are submitting a changed or corrected application in response to an error or warning within the correction time window.



Application Deadline Plus Three to Five Weeks

Within 15 working days after the electronic receipt date, your application should appear in the eRA Commons. Within five weeks of the receipt date, the Commons should show an assignment to a review panel, the date the panel meets, the primary assignment to an NIH IC, and your assigned IC program and grants management staff.

If your application does not appear in the Commons within 15 working days, or if the assignment information does not appear within five weeks, contact the CSR referral office, preferably by email so you have a communication record. Now is also the time to contact the CSR referral office if you have concerns about your application's IC assignment. Find out why if the IC assignment is not what you requested in your cover letter.

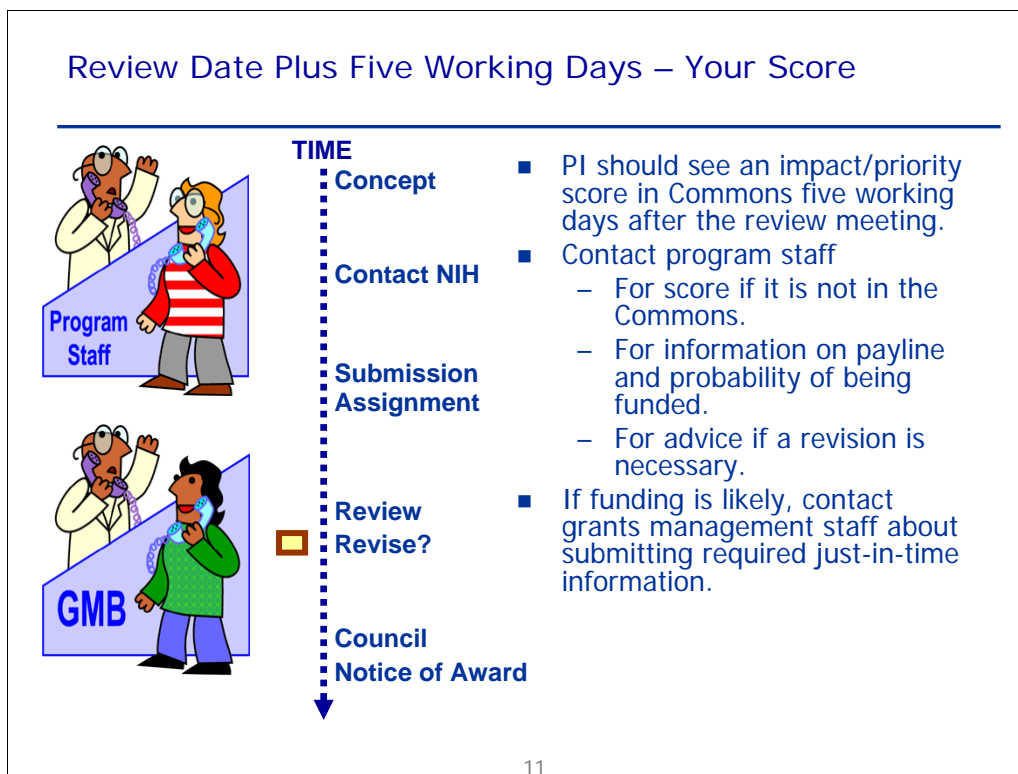


At Least Seven Weeks Before Review

There is a limited window after submission, up to seven weeks before review, when you may be able to provide additional information or correct or update some information in your application. If you discover such a need, don't wait – contact the SRO as early as possible with your request. The new information better be important or you risk the ire of reviewers who have to read more information.

Check the CSR Roster to see who will be on your review panel. This is the time for you to request the exclusion of specific reviewers but you have to provide good reasons. Your cover letter should have documented the knowledge about specific areas in your application needed to review your application. If the roster does not appear to have reviewers with this knowledge, you should request that the SRO recruit additional reviewers. Send an email to document your request. Do not wait until after the review!

Be aware that the SRO is under no obligation to agree to your requests. However, failure to honor your requests is justification for your asking for re-review by another SEP.



Review Date Plus Five Working Days – Your Score

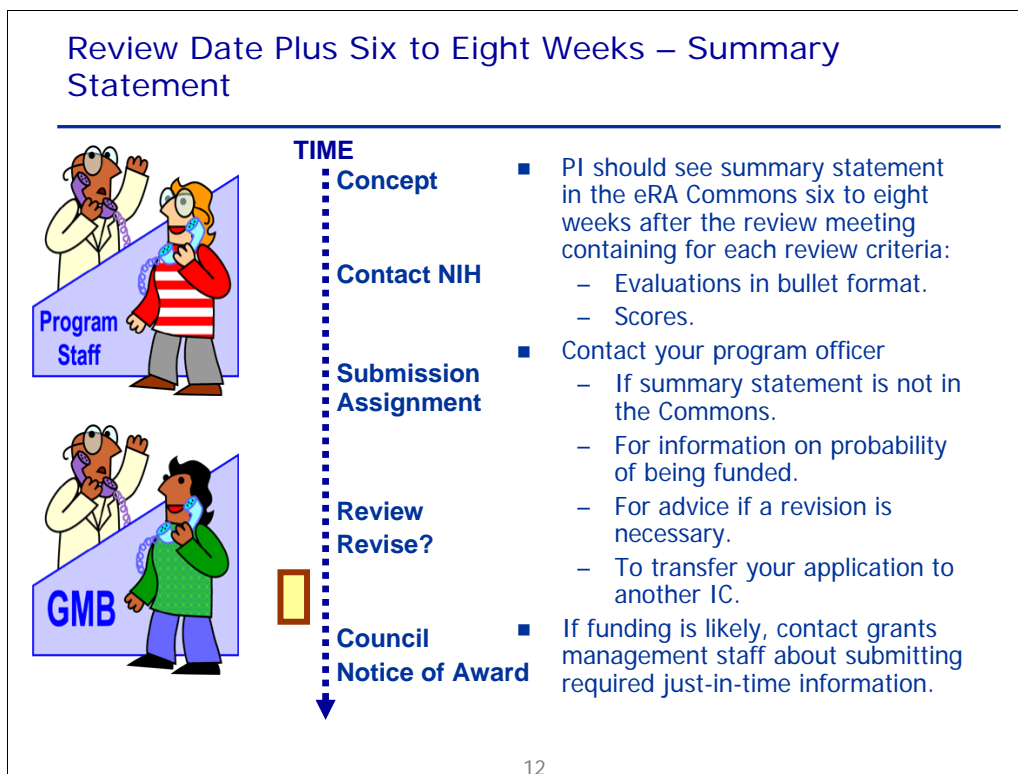
An overall impact/priority score should appear in the PI's Commons account within five working days after the review meeting. Be aware that the score is not available to the Signing Official. If your score has not appeared within five working days, you can call or email your program officer listed in the Commons to identify the delay.

Ask your program officer about the current payline and the probability of your application's being funded. If you are told that your application is not likely to be funded, ask for advice on revising and resubmitting your application even though a summary statement will probably not appear in the Commons for another five to seven weeks.

If you are told that you are likely to be funded, contact your grants management specialist to review the just-in-time information that you will need to provide before we issue an award.

Although program officers do not participate in the review process, they often attend application review meetings. When they do, they can provide you with informal and sometimes more blunt feedback from the review than you will read in the summary statement.

If a program officer believes in the value of your proposal, she or he may be your advocate for funding if your application is only slightly beyond the payline.



Review Date Plus Six to Eight Weeks – Summary Statement

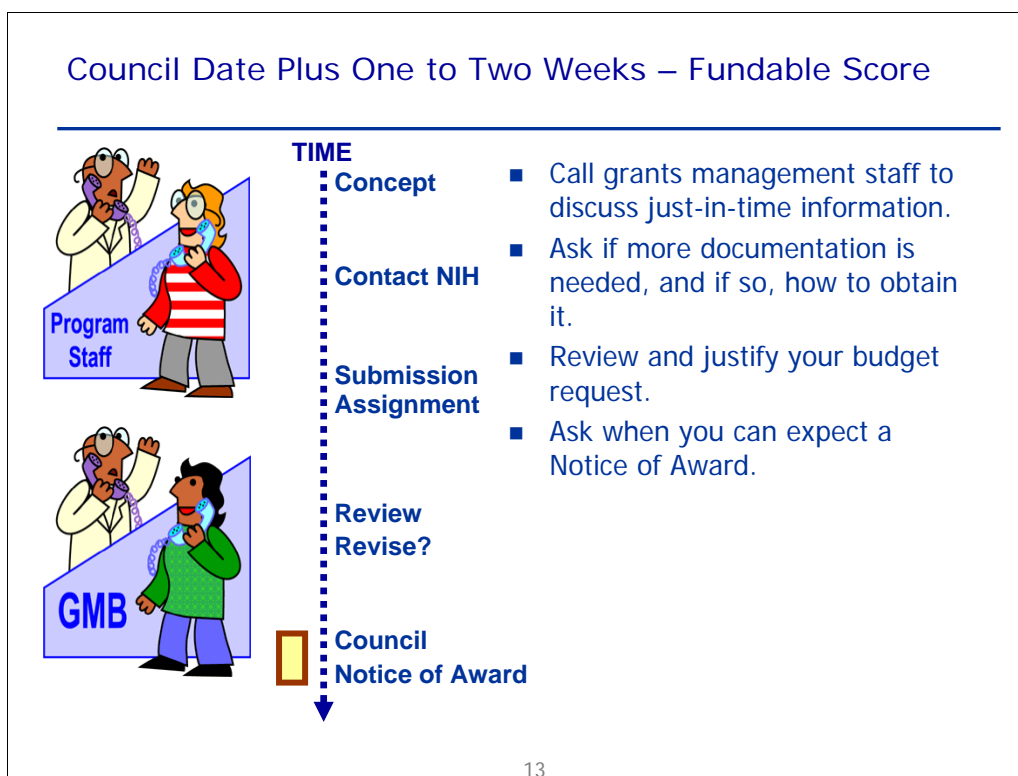
Your summary statement should appear in the Commons within six to eight weeks after the review meeting.

In addition to an overall impact/priority score, your summary statement contains evaluations in bullet format and scores for each review criteria.

If your summary statement has not appeared in the Commons after eight weeks, contact the program officer listed in the Commons to inquire about the delay.

Ask your program officer about the probability of funding and discuss revising your application if funding is unlikely. If your application has a good score but your assigned IC will not fund it, ask if it can be transferred to another IC for funding.

If funding is likely, you should contact your grants management specialist to review the just-in-time information that you will need to provide before NIH issues an award.



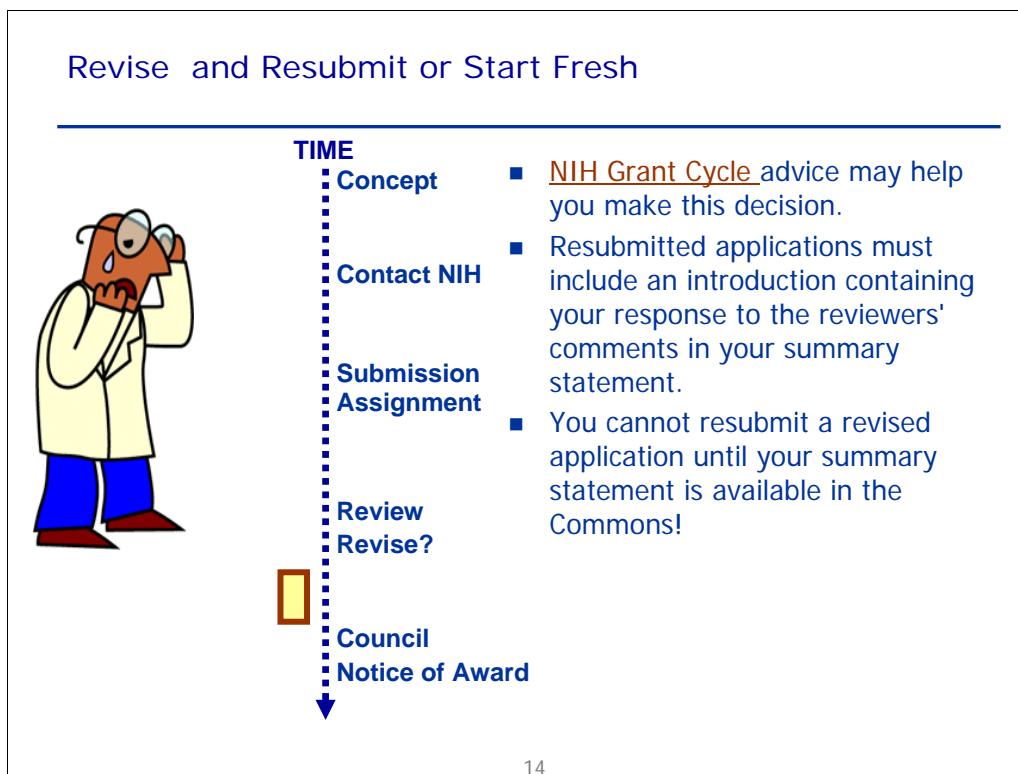
Council Date Plus One to Two Weeks – Fundable Score

Although you should have a pretty good idea of whether your application is in line to be funded based on its overall impact/priority score and your communication with your program officer, there are additional gates your application must pass through before receiving an award.

An IC's Council generally approves all scored applications unless compliance issues are raised in the review. Next, an IC's budget office determines the funding available and provides grants management staff a list of applications that can be considered for funding. Grants management must verify that you meet all the requirements for funding. This gate is the one where many SBIR or STTR applications are delayed or blocked. If you haven't been contacted by a grants management specialist, this may be your fate too.

Call your grants management specialist to confirm that you meet all the requirements for funding. If you are missing anything, find out what documentation is needed. Review and justify your budget request.

Ask when you can expect a Notice of Award.



Revise and Resubmit or Start Fresh

If your application will not be funded, you need to decide whether to revise and resubmit or to start fresh with a new idea.

See the NIH Grant Cycle advice for help on making this decision.

You are allowed only a single revision so consider carefully before rushing to respond to reviewers' comments. See my Tips module to avoid common application errors.

Resubmitted applications must include an introduction containing your response to the reviewers' comments in your summary statement.

It follows that you cannot resubmit a revised application until your summary statement is available in the Commons!

More Presentations



TOPICS

- Basic Information
- Managing the NIH Timeline
- Writing for Reviewers
- FY2008 Data
- Tips and Tricks
- More than SBIR/STTR Funds
- Small Business Funds for Academic Investigators

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Thank you for watching this module. Close this window to select another topic.